

U.S. Application Serial No.: 08/102,390
Second Communication Regarding Status of Application

EXHIBIT F

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTSAPPLIED RESEARCH SYSTEMS ARS
HOLDING, N.V.,

Plaintiff,

v.

CELL GENESYS, INC. AND
TRANSKARYOTIC THERAPIES, INC.,

Defendants.

C.A. NO. 04 11810 MLW

FIRST AMENDED COMPLAINT

Plaintiff Applied Research Systems ARS Holding N.V. (hereinafter "ARS"), for its First Amended Complaint against defendants Cell Genesys, Inc. (hereinafter "Cell Genesys") and Transkaryotic Therapies, Inc. (hereinafter "TKT"), states as follows:

THE PARTIES

1. ARS is a company organized and existing under the laws of the Netherlands Antilles and having its principal place of business c/o ABN AMRO Trust Company (Curacao) N.V., Pictermaai 15, P.O. Box 4905, Curacao, the Netherlands Antilles.
2. On information and belief, Cell Genesys is a corporation organized and existing under the laws of Delaware with its principal place of business at 500 Forbes Boulevard, South San Francisco, California.
3. On information and belief, TKT is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 700 Main Street, Cambridge, Massachusetts.

JURISDICTION AND VENUE

4. This Action arises under the patent laws of the United States, Title 35, United States Code. This Court is vested with subject matter jurisdiction in this Action pursuant to 35 U.S.C. §146 and 28 U.S.C. §§1331 and 1338(a).
5. On information and belief, Cell Genesys and TKT are subject to personal jurisdiction in this judicial district. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391, 28 U.S.C. § 1400(b) and Fed. R. Civ. P. 4(k)(2).

BACKGROUND

6. This Action against Cell Genesys arises from the June 22, 2004 Decision on Preliminary Motions ("the Decision") of the U.S. Patent and Trademark Office Board of Patent Appeals and Interferences ("the Board") in Interference No. 105,114 ("the '114 Interference"). A copy of the Decision is attached hereto as Exhibit 1. The subject matter of the '114 Interference was defined by Count I, which was directed to "a method according to claim 2 or claim 3" of ARS's U.S. Patent No. 5,272,071 ("the '071 Patent") (attached hereto as Exhibit 2), which names as inventor Scott C. Chappel. Claims 2 and 3 of the '071 Patent recite:

2. A method of modifying the expression characteristics of a predetermined gene within the genome of a cell line, comprising inserting a DNA construct into said genome by homologous recombination, said DNA construct comprising a DNA regulatory segment capable of modifying the expression characteristics of said gene when operatively linked thereto, as compared to its existing DNA regulatory segment, and a DNA targeting segment homologous to a region of said genome within or proximal to said gene, wherein said construct is inserted such that said regulatory segment is operatively linked to said gene of interest.

3. A method of modifying the expression characteristics of a predetermined gene within the genome of a cell line,

comprising inserting a DNA construct into said genome by homologous recombination, said DNA construct comprising an expressible, amplifiable gene capable of amplifying said gene when inserted in sufficiently close proximity thereto, and a DNA targeting segment homologous to a region of said genome within or proximal to said gene, wherein said construct is inserted such that said amplifiable gene is in sufficiently close proximity to said gene of interest to cause amplification thereof when said amplifiable gene is amplified.

7. Plaintiff ARS is the assignee and real-party-in-interest of the '071 Patent.
8. Cell Genesys purports to be the assignee and real-party-in-interest for U.S. Patent Application No. 08/102,390 ("the '390 Application") which was also at issue in the '114 Interference.
9. On information and belief, in June 2002 Cell Genesys and TKT entered into an agreement wherein TKT purchased a license under the '390 Application, whereby TKT is obligated to pay Cell Genesys more than \$10 million if Cell Genesys is able to obtain issuance of the claims of the '390 Application that were found unpatentable by the Board in the Decision. During the '114 Interference an officer of TKT admitted that TKT had a business relationship with Cell Genesys and that based on their licensing agreement, TKT had a financial interest in Cell Genesys's success in the '114 Interference.

COUNT I

DISSATISFACTION WITH THE DECISION

10. Plaintiff ARS repeats and re-alleges the allegations contained in paragraphs 1-9 as if fully set forth hereinafter.
11. ARS is dissatisfied with the Decision and seeks reversal thereof insofar as the Board found that claims 1, 2, 5-7, 9-20, 22, 23, 25, 26, 32-39, 52-54, 56, and 57 of the '071

Patent are "unpatentable [sic: invalid]" over certain prior art, and insofar as the Board ruled against ARS on certain motions, claim construction issues and evidentiary issues.

12. Specifically, ARS seeks reversal of (i) the Board's decision that the term "cell line" in ARS's involved claims "does not exclude prokaryotes such as bacteria, single-celled eukaryotes such as yeasts and molds, or any other prokaryotic and eukaryotic microorganisms" and "means nothing more than a cell culture derived from a single cell, preferably a permanent cell culture derived from a single cell." (See page 21 of Exhibit 1 attached hereto); (ii) the Board's dismissal of ARS's Preliminary Motion 7 and its finding that ARS is only entitled to benefit of the December 21, 1990 filing date for the claims of the '071 Patent (see page 125 of Exhibit 1); (iii) the Board's findings that Claims 1, 2, 5-7, 9-20, 22, 23, 25, 26, 32-39, 52-54, 56, and 57 of the '071 Patent are invalid over the "Japan" reference (Japanese Patent Publication 1-215280) (see page 79 of Exhibit 1) or invalid over the "Japan" reference in combination with other prior-art references (see pages 86-87 and 125 of Exhibit 1); (iv) the Board's decision that Claims 2, 17, 19, 20, 26, 28, 31 and 52-54 of the '071 Patent are invalid over the "Ribaud" reference (see page 54 of Exhibit 1); (v) the Board's decision that Claims 1, 2, 5, 9, 17, 18, 22, 25, 26, 28 and 32 of the '071 Patent are invalid over the "Nasmyth II" reference, alone or in combination with the "Nasmyth I" reference (see page 58 of Exhibit 1); (vi) the Board's decision that Claims 2, 17 and 26 of the '071 patent are invalid over the "Cid" reference (see page 68 of Exhibit 1); (vii) the Board's dismissal of ARS's Preliminary Motions 1 and 2 as regards Claims 105 and 107-112 of Cell Genesys's involved application, and denial

of those motions as to Claim 106 of that application (*see* pages 136-140 of Exhibit 1); and (viii) the Board's dismissal of ARS's motions to suppress the Heartlein and Rowland Declarations (*see* pages 140-141 of Exhibit 1).

COUNT II

INFRINGEMENT OF THE '071 PATENT BY TKT

13. On information and belief, since the issuance of the '071 Patent on December 21, 1993, TKT has infringed one or more claims of the '071 Patent (including one or more of claims 3, 4, 8, 21, 24, 27-31, 40-51, 55, and 58 that were specifically found patentable by the Board in its Decision in the '114 Interference) by making, using, selling, and/or offering for sale the methods, cell lines, and/or DNA constructs claimed therein.
14. TKT's direct infringement, contributory infringement and/or inducement to infringe one or more claims of the '071 Patent has injured ARS, and ARS is entitled to recover damages adequate to compensate it for such infringement.
15. On information and belief, TKT will continue to infringe one or more claims of the '071 Patent unless and until this Court enters an injunction prohibiting further such infringement, and specifically enjoining further manufacture, use, offer for sale or sale of the methods, cell lines, and/or DNA constructs claimed in the '071 Patent.
16. On information and belief, TKT has been aware of the '071 Patent and has nonetheless infringed one or more claims of the '071 Patent with knowledge of those claims' scope and their applicability to TKT's activities and/or products. As a consequence, TKT's infringement, contributory infringement, and/or induced infringement has been willful and deliberate.

PRAYER FOR RELIEF

ARS prays for a judgment ordering and decreeing, *inter alia*, that:

- (a) Claims 1, 2, 5-7, 9-20, 22, 23, 25, 26, 32-39, 52-54, 56, and 57 of the '071 Patent are not invalid;
- (b) TKT has infringed the '071 Patent;
- (c) ARS be awarded damages adequate to compensate it for the infringement by TKT that has occurred, together with prejudgment interest from the date such infringement began;
- (d) ARS be awarded increased damages as permitted under 35 U.S.C. § 284;
- (e) This case be deemed exceptional and ARS be awarded its attorneys' fees and costs as provided by 35 U.S.C. § 285;
- (f) TKT and its subsidiaries, successors, affiliates, agents, servants, employees and all those persons or entities in active concert or participation with it be permanently enjoined from further infringement of the '071 Patent; and
- (g) ARS be awarded such other relief in law and equity as the Court may deem just under the circumstances.

Date: August 30, 2004

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a true copy of the above document was
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Fred A. Kelly, Jr.

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